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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,758	05/15/1998	DENNIS R MORRISON	MSC-22939-1-	8692
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NASA JOHNSON SPACE CENTER MAIL CODE HA 2101 NASA RD 1 HOUSTON, TX 77058			EXAMINER SHARAREH, SHAHNAM J	
			ART UNIT 1617	PAPER NUMBER

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/079,758

Applicant(s)

MORRISON ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 9-35, 37-41, 43, 44, 49, 50, 55, 56, 69 and 72-94 is/are pending in the application.
- 4a) Of the above claim(s) 44, 49, 50, 55, 56, 79-82 and 88-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 9-23, 26-35, 37-41, 43, 69, 72-78, 83-87, 93 and 94 is/are rejected.
- 7) ☒ Claim(s) 24-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Amendment filed on September 15, 2004 has been entered.

Claims 1, 6, 9-35, 37-41, 43-44, 49-50, 55-56, 69, 72-94 are pending. Claims are subject to a restriction requirement. Applicant has elected the Group I in Paper filed on June 30, 2003. Claims 44, 49-50, 55-56, 79-82, 88-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on June 30, 2003. Applicant has further made an election of species on Nov 26, 2003. Accordingly any polymeric moiety recited as an outer membrane in instant claim 6 is viewed to meet the limitation of outer membrane polymer. Claims 1, 6, 9-35, 37-41, 43, 69, 72-78, 83-87, 93-94 are under consideration.

Any rejection that is not discussed in this Office Action is considered obviated in view of the amendments.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 6, 9-35, 37-41, 43, 69, 72-7, 83-87, 93-94 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There does not appear to be a written description of the claim limitation

"wherein a polymer of the polymer outer membrane does not extend from the polymer outermembrane into the microcapsules such that the two or more liquid phases are not dispersed by the polymer," in the application as filed.

During prosecution of an Application, if a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, Examiner should conclude that the claimed subject matter is not described in that application. See MPEP 2163. Applicant is noted that any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem.*, 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement.

Here Applicant has relied on Fig. 1A to provide support in the instant specification for the newly added limitation. However, Fig. 1A by itself does not adequately meet the requirement under the 35 USC 112 1st paragraph. As the initial matter, Fig. 1A is merely a schematic of microcapsules containing magnetic particle that is heated by exposure to an electromagnetic field. The Specification further explains at page 45, last paragraph that the outer polymer membrane encloses one or more internal liquid phases. There is no reference anywhere in the specification directed to

the characteristics of the outer membrane wall and whether there is any extension of such wall into the internal of the microcapsule.

Moreover, the recited limitation appears relative in nature. There is no clear guideline as to what is the scope of the phrase "...extend from the polymer outer membrane into the microcapsule." It is not clear how such extension is measured and what is exactly excluded.

Further, the phrase added attempts to describe what the microcapsule is not rather than what it really is. Applicant is reminded that any negative limitation or exclusionary proviso must have basis in the original disclosure. Here, the mere absence of a positive recitation is not a basis for the exclusion. Therefore, since the original description fails to ascertain the metes and bounds of the claims and also clearly describe the claimed limitations, the Examiner takes the position that the added subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 9, 11, 14, 17, 21-23, 30-35, 37-38, 40, 73-75, 85-86 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinty et al US Patent 5,288,502.

3. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant argues that the instant microcapsules differs from

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those of McGinty because the “polymer of the outer membrane of the instantly claimed microcapsules does not extend from the polymer outer membrane into the microcapsule such tat the liquid phase are not dispersed by the polymer.” (see Arguments at pagew 17-18).

In response Examiner states that the claims are directed to a composition. All elements of the claimed compositions are described in McGinty’s microcapsules. Therefore, McGinty’s microcapsules inherently possess all functional and design characteristics of the instant microcapsules.

4. Applicant also adds that the process of making McGinty’s microcapsules differ from those of the instant claims; thus, leading to a polymeric wall that disperses the internal liquid phases (see Arguments at page 18). In response Examiner states that the claims are not directed to methods of preparing a microcapsules. Rather, the claims are directed to a product. Therefore, Applicant’s arguments are not commensurate with the scope of the claims.

Further the McGinty teaches all elemental limitations of the instant products. Applicant has not met the burden of showing how the instant microcapsules with identical limitations as those of the prior art would have led to structural differences as claimed.

5. Applicant is informed that any microcapsule that contains these three elements would also inherently meet all functional limitations set forth in the pending claims, because the claimed function are properties of one of the above recited elements.

McGinty discloses multi-phase polymeric microspheres that anticipate the limitations of the instant claims (abstract). McGinty's 'microspheres comprise internal immiscible liquid phase in the form of microemulsions (see col 4, lines 54-67). McGinty's emulsion contains a water phase and an oil phase, thus it contains at least two internal phases (multi-phase microspheres).

McGinty teaches an outer membrane polymeric shell (see Table 1, lines 40-51 describing the polymeric wall). Figures 5-8, 11 describe formation of a wall with clear boundaries surrounding the internal core of the microcapsules. The table 1 attests the fact that there exists a polymeric wall around the internal core.

6. The instant claims does not exclude the polymeric wall of McGinty's microcapsules because there exists no difference in the thickness or the polymeric material of the prior art wall and those of the instantly claimed microcapsules.

McGinty comprise an internal immiscible liquid phase that comprises Tween 80 (2% sorbitan monooloeate/20 moles ethylene oxide) and/or Span 80 (sorbitan monooleate). (see Table 1, col 15; col 14, lines 1-10). Such element meets the energy absorbing limitation of the instant claims. Thus, McGinty meets the limitations of the instant generic claims.

McGinty also provides for the limitations of the dependent claims. For example, McGinty discloses the use of soybean recited as an halogenated oil in the pending claim 38. (see col 14, line 4 and Table 1). McGinty teaches the use of drug, drug precursors or diagnostic agents including procainamide, an anesthetic, interferon, TPA or urokinase and steroid releasing hormones (claims 1-15). The limitations of claims 93-

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94 are also a function of the components employed by McGinty. In fact figure 6C of McGinty suggests formation of multilamellar phases. Since McGinty teaches microcapsules with all elemental components of the instant microcapsules, McGinty anticipates all functional and design characteristics of the instant microcapsules.

Claim Rejections - 35 USC § 103

Claims 1, 6, 9-23, 26-35, 37-41, 43, 69, 72-78, 83-87, 93-94 stand rejected under 35 U.S.C. 103(a) as being unpatentable over McGinty in view of Grinstaff et al US Patent 5,665,383.

7. Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant appear to be arguing that one of ordinary skill in the art would not modify McGinty by adding the bioactive of polymeric moieties taught in Grinstaff because any such modifications would interfere with the intended purpose of McGinty's invention. (see Arguments at page 22).

In response Examiner state that first of all, McGinty all elemental components of the instant claims. Therefore, provides ample motivation in the art to use suitable bioactive such as anti-cancer agents, antibiotics, antivirals, magnetic particles (see col 28, lines 1-50). Therefore, motivation to modify McGinty's formulations comes directly from the teachings of McGinty.

Further, Grinstaff is merely used to enumerate such bioactive agents and polymeric moieties that are frequently used in the art inside a polymeric shell. (see abstract, col 8, lines 20-31). For example, such polymers include polyethylene glycols, dextrans, polyvinyl alcohols, or polyvinylpyrrolidone. (see col 8, lines 40-52; col 9, lines

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11-19, col 12 lines 10-33 and lines 60-67; col 27; examples 10-11). Examiner viewed such moieties as functional art recognized equivalents and certainly interchangeable in the art of preparing microcapsules.

Grinstaff also teaches bioactive agents including various anticancer, antibiotics, antiviral etc...(see col 13, lines 41-col14, line30). Radio contrasts taught by Grinstaff include paramagnetic iron (see col 7, lines 10-16; col 16, lines 51-66; example 47). In addition to meeting the limitations of the instant claims 27 and 72, the bioactive agents of Grinstaff (i.e. paramagnetic iron) and the polymeric moieties of Grinstaff (i.e. PVP) also fall within the scope of those moieties enumerated in McGinity. (see col 27, line 30-col 28, line 50). Therefore, substituting the bioactive agents of Grinstaff in McGinity's formulation would have been obvious.

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute suitable polymers and bioactive agents of Grinstaff in McGinity's polymeric microcapsules because as suggested by Grinstaff, art equivalent synthetic and natural polymers are expected to provide suitable polymeric shells for drug delivery. Moreover, since both McGinity and Grinstaff illustrate wall characteristics that appear similar to those instantly claimed (see figures), the final product would have met all limitations of the instant claims.

8. Applicant also argues that McGinity teaches away from the presently claimed invention. (see Arguments at page 22). Applicant adds that McGinity leads away from a polymer outermembrane, where the polymer of the polymeric outermembrane does not extend from the outermembrane into the microsphere. (see Arguments at page 23).

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In response, Examiner that McGinity's teachings are not a direct teaching away from the instant claims. In fact, there is no clear distinction between the limitation that applicant is arguing about and the wall described in McGinity. Thus, Applicant's conclusion is not correct.

First, Applicant appears to misinterpret what it means to "teach away" from a patented invention. Generally, "disclosed examples and preferred embodiments do not constitute a teaching which is away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 169 USPQ 423 (CCPA 1971). "In general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the results sought by the applicant." *In re Gurley*, 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994).

Here, the mere fact that there is an alternative means of improving drug delivery as described by McGinity does not preclude modifications of the outermembrane walls of McGinity or the usage of suitable bioactive agents and polymeric moieties describe in Grinstaff in McGinity's formulations. Indeed McGinity illustrates such figures that appear similar to those instantly claimed. Grinstaff also teaches polymeric shells that appear similar to those instantly claimed. Therefore, the wall characteristics does not

Specifically, the portions of McGinity's patent that Applicant characterizes as a "leading away" (col 9, lines 1-11; col 12, lines 62-64) does not discourage one of ordinary skill in the art to employ the polymeric membranes or method steps that provides suitable wall characteristics. In fact, McGinity uses polymers that fall within the

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scope of the instant outermembrane polymers. McGinity generically recites the use of other suitable bioactive agents. Thus, there is no direct teaching in McGinity's patent.

Since all elements of the claimed invention are describe in McGinity one of ordinary skill in the art would have most likely performed further experimentation to determine what is the optimal polymeric wall characteristics and apply suitable drugs that could be delivered via such delivery system.

Second, Applicant has not provided any evidence or explains how the disclosures of the prior art show that their claimed invention is not likely to provide the wall characteristics as describe in the instant claims, when McGinity in fact provides figures of microspheres that appear identical to those instantly claimed. Thus, Examiner does not see a statement in McGinity showing that the instantly claimed microspheric wall or the use of the suitable bioactive agents would have been a less attractive option for drug delivery. Therefore, Examiner concludes that a person of one ordinary skill, upon reading the McGinity reference, would not have been discouraged from employing suitable bioactive or polymeric moieties described in Grinstaff.

Claim Objections

9. Claims 24-25 are objected to as being dependent upon a rejected base claim.

Conclusion

No claims are allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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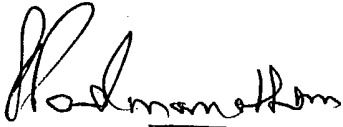
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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